Endoscopy
Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810

978 749 1000
978 749 1599 Fax
www.smith-nephew.com

K060777

We are smith&nephew

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew 660HD Image Management System
Date Prepared: March 17, 2006

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Kathleen Burns
Regulatory Affairs Specialist
Phone: (978)474-6301
Fax: (978)749-1443

C. Device Name

Trade Name:	Smith & Nephew 660HD Image Management System
Common Name:	Smith & Nephew 660HD Image Management System
Classification Name:	Endoscope and Accessory, Image Capture

D. Predicate Devices

The Smith & Nephew 660 Image Management System is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution: Dyonics Vision 635 Image Management System.

E. Description of Device

The Smith & Nephew 660HD Image Management System is a computer based system which interacts with medical camera systems and non-medical devices such as A/V equipment, audio equipment, printers and monitors. The 660HD System provides a convenient means to capture video data from the medical camera system and archive it to removable storage media. In addition the 660HD System provides a mechanism to transfer data to a network location and to import/export procedure information from certain repository systems that are already part of the Hospital Information System.

F. Intended Use

The Smith & Nephew 660HD Image Management System is intended to capture intraoperative still and motion images.

G. Comparison of Technological Characteristics

Smith & Nephew 660HD Image Management System has the same fundamental scientific technology and substantially equivalent as the predicate device identified above.

H. Summary Performance Data

All verification and validation data demonstrates that the device is safe and effective and performs as intended.

The Smith & Nephew 660HD Image Management System conforms to the following voluntary standards:

IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety (1998) + Amendment 1 (1991) + Amendment 2 (1995) (UL 2601-1)

IEC 60601-1-1 Medical Electrical Equipment – Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems (1992) + Amendment 1 (1995), (2000)

IEC 60601-1-2 (2001-09) 2nd Edition Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements & Tests (2001)

UL 60601-1 (2003): Medical Electrical Equipment – Part 1: General Requirements for Safety

CAN/CSA 22.2 No. 601.1 Medical Electrical Equipment – Part 1: General Requirements for Safety (1990) + Supplements No. 1-94 (1994)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2006

Smith & Nephew, Inc.
Endoscopy Division
c/o Ms. Kathleen Burns
Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K060777
Trade/Device Name: Smith & Nephew 660HD Image Management System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 17, 2006
Received: March 22, 2006

Dear Ms. Burns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

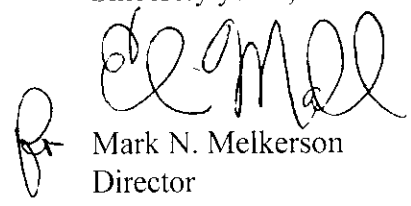
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060777

Indications for Use

510(k) Number (if known): _____

Device Name: Smith & Nephew 660HD Image Management System

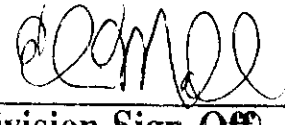
Indications For Use:

The Smith & Nephew 660HD Image Management System is intended to capture intraoperative still and motion images.

Prescription Use ___X_____ Use	AND/OR	Over-The-Counter
(Per 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060777